



JUL 7 2003

Jonathan W. Emord, Esq.
Emord and Associates, P.C.
5282 Lyngate Court
Burke, VA 22015

Re: Petition for omega-3 fatty acids and coronary heart disease health claim

Dear Mr. Emord:

This letter acknowledges receipt on June 23, 2003 by the Food and Drug Administration (FDA) of the petition you submitted, on behalf of Wellness Lifestyles, Inc. and Life Extension Foundation Buyers Club, Inc. pursuant to Section 403(r)(4) and 403 (r)(5)(D) of the Federal Food Drug and Cosmetic Act (FFD&C Act)(21 U.S.C. § 343(r)(4) and 21 U.S.C. § 343(r)(5)(D)). The petition requests FDA authorization of a health claim for conventional foods and dietary supplements relating consumption of omega-3 fatty acids (specifically eicosapentaenoic acid ("EPA") and docosahexaenoic acid ("DHA")) to reduced risk of coronary heart disease.

This petition is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the FFD&C Act and 21 CFR 101.70(j)(2), within 100 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review, or to deny the petition. A denial may be by either FDA action within the initial 100-day period, which ends on October 1, 2003, or by a lack of action by FDA within the initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

Please feel free to contact me at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,

Tomoko Shimakawa, Sc.D.
Epidemiologist
Division of Nutrition Programs and Labeling
Office of Nutritional Products, Labeling
and Dietary Supplements
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